This Page Is Inserted by IFW Operations and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problem Mailbox.



PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6:
A61B 5/0205

A1

(11) International Publication Number: WO 95/33403

(43) International Publication Date: 14 December 1995 (14.12.95)

(21) International Application Number:

PCT/SE95/00629

(22) International Filing Date:

1 June 1995 (01.06.95)

(30) Priority Data:

9401959-3

7 June 1994 (07.06.94)

SE

(71)(72) Applicant and Inventor: BADER, Gaby [SE/SE]; Lilla Danska Vägen 12, S-412 74 Gothenburg (SE).

(74) Agents: JOHANSSON, Lars, E. et al.; Bergenstråhle & Lindvall AB, P.O. Box 17704, S-118 93 Stockholm (SE). (81) Designated States: FI, JP, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published

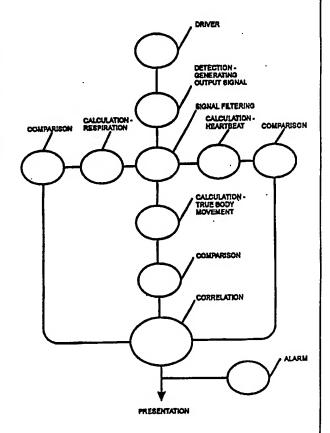
With International search report.

In English translation (filed in Swedish).

(54) Title: METHOD AND APPARATUS FOR MONITORING AND ESTIMATING THE AWAKENESS OF A PERSON

(57) Abstract

For monitoring and estimating a person's wakefulness, a stationary pressure sensitive means (2, 3, 4) contacts part of that person's (1) body, and generates a signal in correspondence to that person's body movements relative to said means. A detector/filter circuit (5) connected to said means, separates signals corresponding to true body movements, hearbeat-related body movements, and respiration-related body movements. Calculation and comparison circuits (6, 9; 7, 10; 8, 11) are adapted to receive these signals and compare them with previously received signals to determine possible changes. A correlator (12) correlates the output signals from the calculation and comparison circuits to produce a resulting change signal which is compared with a preset wakefulness threshold in a threshold detector circuit (13). An alarm device (14) is triggered, when the preset threshold is reached as an indication of a reduced degree of wakefulness.



.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

- AT .	Austria .	GB	United Kingdom	MR	Mauritania	
ΑU	Australia	GE	Georgia	MW	Malawi	
BB	Barbados	GN	Guinea	NE	Niger	
BE	Belgium	GR	Greece	NL	Netherlands	
BF	Burkina Faso	HU	Hungary	NO	Norway	
BG	Bulgaria	IE	Ireland	NZ	New Zealand	
BJ	Benin	IT	Italy	PL	Poland	
BR	Brazil	JP	Japan	PT	Portugal	
BY	Belarus	KE	Kenya	RO	Romania	
CA	Canada	KG	Kyrgystan	RU	Russian Federation	
CF	Central African Republic	KP	Democratic People's Republic	SD	Sudan	
CG	Congo		of Korea	SE	Sweden	
CH	Switzerland	KR	Republic of Korea	SI	Slovenia	
CI	Côte d'Ivoire	KZ	Kazakhstan	SK	Slovakia	
CM	Cameroon	LI	Liechtenstein	SN	Senegal	
CN	China	LK	Sri Lanka	TD	Chad	
CS	Czechoslovakia	LU	Luxembourg	TG	Togo	
CZ	Czech Republic	LV	Latvia	TJ	Tajikistan	
DE	Germany	MC	Monaco	TT	Trinidad and Tobago	
DK	Denmark	MD	Republic of Moldova	UA	Ukraine	
ES	Spain	MG	Madagascar	US	United States of America	
FI	Finland	ML	Mali	UZ	Uzbekistan	
FR	France	MN	Mongolia	VN	Viet Nam	
GA	Gabon		-			

Method and apparatus for monitoring and estimating the awakeness of a person.

TECHNICAL FIELD

The invention relates to a method and an apparatus for monitoring and estimating a person's wakefulness and, thereby, drowsiness.

5

BACKGROUND OF THE INVENTION

It is known, e.g. from the article "Determination of sleep state in infants using respiratory variability", PEDIATR.

RES. 1987, Haddad, GG, JENG, HJ, LAI, TL, MELLINS RB., that in connection with cardiac/respiratory research on infants, changes in the cardiac/respiratory activity at short, instantaneous (REM/Rapid Eye Movement) sleep differ from corresponding changes at calm, deep sleep.

15 BRIEF DESCRIPTION OF THE INVENTION

The object of the present invention is to utilize a corresponding relationship between the cardiac/respiratory function and a person's body movements in order to estimate that person's wakefulness and, thereby, the drowsiness of the person in question.

This is attained by means of the method according to the invention in

- that an electric signal is generated in response to said
 25 person's body movements relative to at least one stationary
 pressure sensitive means which contacts at least a portion of
 said person's body,
- that signals are separated from said electric signal in correspondence to the duration and magnitude of true body
 movements, the amplitude of heartbeat-related body movements as a function of rate, and the amplitude of respiration-related body movements as a function of rate,
- that the duration and magnitude of said true body movements as well as the time-interval between same are measured and compared with previously m asur d corresponding values to determine possible changes,
 - that the amplitude of every heartbeat-related and every respiration-related body movement as well as the time-in-terval b tween at 1 ast two successive heartbeats and respi-

30 possible changes,

rations, are measured and compared with previously m asured corresp nding values to determine possible changes,

- that heartbeat-related and respiration-related changes are correlated with true body movement changes,
- 5 that the resulting change is compared with a preset wakefulness threshold and
 - that an alarm is triggered when the threshold is reached as an indication of a reduced degree of wakefulness.
- 10 The object is also attained by means of the apparatus according to the invention, which comprises
- at least one stationary pressure sensitive means which is adapted to contact at least a portion of said person's body, and to generate an electric signal on its output terminal in response to said person's body movements relative to same,
 - a detector/filter circuit, connected to the output terminal of said at least one stationary pressure sensitive means, and adapted to separate, from said electric signal, signals corresponding to the duration and magnitude of true body
- movements, to the amplitude of heartbeat-related body movements as a function of rate, and to the amplitude of respiration-related body movements as a function of rate, and output these separated signals on corresponding output terminals,
- a first calculation and comparison circuit which is adapted 25 to receive, on its input terminal, said signal corresponding to true body movements, to calculate the duration and magnitude of the true body movements as well as the time interval between same, and to compare these calculated values with previously calculated corresponding values to determine
 - a second and a third calculation and comparison circuit which are adapted to receive, on their input terminals, said signal corresponding to heartbeat-related and respiration-related body movements, respectively, to calculate the
- amplitude of every heartbeat-related and every respirationrelated body movement, respectively, as well as the time interval between at 1 ast two successive heartbeats and respirations, respectively, and to compare these calculated values with previously calculated corresponding values to

determine possible changes,

- a correlator, c nnected to the the utput terminals of said three calculation and comparison circuits, and adapted to correlate heartbeat-related and respiration-related changes with true body movement changes,
- a threshold detector circuit, connected to the output terminal of the correlator, and adapted to compare the resulting change with a preset wakefulness threshold, and
 an alarm device, connected to the output terminal of the
 threshold detector circuit, and adapted to trigger alarm when the preset threshold is reached as an indication of a reduced degree of wakefulness.

The advantage of the invention is that, by means of the

method and the apparatus according to the invention, it is

possible, in an efficient manner, to monitor the degree of

wakefulness of e.g. drivers of different types of vehicles

(cars/buses/trains/boats/aircrafts) without disturbing the

monitored person in that also the body movements of the

monitored person are taken into account. Other suitable

groups to monitor may be persons having a sedentary occupa
tion such as students, guards, operators in process plants,

nuclear power plants, etc.

25 Moreover, the invention can be applied when studying syndroms characterized by state-dependent changes in heart and respiratory rate, such as sleep apnea or autonomic neuropathy.

Of course, it is also possible to apply the invention to

30 other types of analyses aiming at establishing the state of
wakefulness within different occupational groups or at different illnesses or other types of sleep disturbances.

BRIEF DESCRIPTION OF THE DRAWING

35

The invention will be described below in connection with an embodiment with refer nce t the appended drawing on which

Fig. 1 shows a flow chart of the method according to th

PCT/SE95/00629

4

invention,

Figs. 2a-f are diagrams of variations of cardiac R-R at different sleep stages, and

5

Fig. 3 shows a block diagram of an embodiment of an apparatus according to the invention.

PREFERRED EMBODIMENT

10

The invention is based on an investigation of a number of adults in a sleep laboratory using paper polysomnography and an equipment marketed under the trademark "SleepBox".

15 Different sleep stages were determined in accordance with classic neurophysiologic criteria. Cardiac R-R intervals, i.e. the time intervals between two heartbeats, and respiratory intervals as well as the amplitude of the waves were measured both manually and by means of wave detectors in 20 epochs of 30 - 60 s. The intervals were determined over 15 min periods for each sleep/wakefulness stage. It is of course also possible to determine the intervals continuously which is done in connection e.g. with computer analysis. Statedependent beat-to-beat patterns were studied by plotting each 25 R-R and respiratory interval against the previous interval. The results showed the highest beat-to-beat and respiratory variability during wakefulness and a large dispersion during REM with a progressive decrease during sleep, related to the sleep level. The smallest variations were attained on deep 30 sleep.

In view of these results, a decision rule was developed for classifying different sleep stages according to the cardiac R-R and respiratory variability. This rule has been tested on normal healthy adults and the results show that more than 80% of the epochs are classified c rrectly.

A process in accordance with the method according to the inv ntion is described below with reference to Fig. 1. The

WO 95/33403 PCT/SE95/00629

5

described method is normally implemented by means of software. A pers n is sitting and driving e.g. a car or another
vehicle. Pressure sensitive, stationary plates or sensors are
installed in the seat or the back of the seat and where

5 appropriate possibly in a safety belt. The plates can be PVDF
films possibly in combination with electrostatic plates. The
driver's body movements cause different pressures against the
plates which continuously register the pressure and the
movements.

10

In a manner known per se, the plates generate electrical output signals which are detected and analyzed. Besides movements of the body, also the cardiac function and the respiratory function can be detected by means of these output 15 signals. The amplitude and rate of the cardiac function are detected as are the amplitude and rate of the respiratory function. Depending on the driver's degree of wakefulness, the magnitude of these parameters varies. The signals are now to be analyzed and can either be analyzed directly or be 20 stored in a memory for later transmission or be transferred simultaneously by wireless communication to a personal computer for storing and further processing of data. Analysis and processing of the signals take place continuously in a system which is designed for the purpose and coupled to the 25 plates via wires or wirelessly connected to the plates, in which system each signal is analyzed independently of the other signals. The rate and amplitude of each heartbeatrelated or respiration-related body movement, are calculated. The time intervals between two successive signals, are 30 measured. Upon registering true body movements, the duration of the movements as well as the magnitude of the movements, are measured. Moreover, the time interval between movements is measured. The body movements are classified in accordance with duration and magnitude.

35

Moreov r, in the system, the variations in time interval, amplitude and rate for each heartbeat and respiration, are compared with corresponding values for pr vious r successive heartbeats and r spirati ns. Respiration and heartbeat

PCT/SE95/00629

changes are c rrelated with b dy movement changes. In order to btain further information, it is also possible to register the pressure of the person's head against a head rest, if any.

5

By statistical analysis including i.a. multiple regression, it can be shown that there is a direct relationship between said parameters and changes in the person's degree of wakefulness. The system continuously compares processed data with the previously obtained standard material. Upon a reduced degree of wakefulness an alarm is triggered at a certain threshold level, which alarm can be an audio signal and/or a light signal.

Analysis and processing of data are carried out by means of a computer system controlled by an analysis program. When needed, the program reconstructs all signals which can then be presented on a screen (not shown) connected to the system. Also, the final result can be presented in the form of histograms or statistic tabels.

Figs. 2a-f show the variation when measuring cardiac R-R in relation to the previous interval in different stages of sleep/wakefulness.

25

From Fig. 2a it is apparent that the variation is largest when awake. Fig. 2b shows the variation during REM, while Figs. 2c-e show the variation at different sleep stages. As apparent, the variation decreases with deeper sleep. Fig. 2f shows that the variation increases at the reawakening. The horizontal axis indicates RR, i.e. the value actually measured. The vertical axis indicates RR+1, i.e. the value measured in the preceding interval.

In Fig. 3, in the form of a block diagram, an embodiment of an apparatus according t the invention, is shown. The emb diment r lates t monitoring a driver 1 f a vehicle. As mentioned above, the driver 1 is in c ntact with pressure sensitive plates 2 - 4, which detect the driver's 1 body

movements. The plates 2-4 generate output signals which ar det cted and filtered in respect of signal type in a detector/filter circuit 5. The different signal types are those corresponding to true body movements, heartbeat-related body 5 movements and respiration-related body movements. From output terminals on the filter circuit 5, the signals are supplied to input terminals of calculation circuits 6-8 for calculation, in the circuit 6, of rate and amplitude for each heartbeat as well as the time interval between the heart beats, in the circuit 7, of rate and amplitude for each respiration as well as the time interval between the respirations, and, in the circuit 8, of the duration and magnitude of a true body movement as well as the time interval between true body movements. Comparison circuits (comparators) 9-11 15 receive on their input terminals, output signals from the circuits 6-8 and compare for each function, i.e. hearbeatrelated body movements, respiration-related body movements, and true body movements, the time interval variation, the variation in amplitude for heartbeat-related body movements 20 and respiration-related body movements, respectively, with corresponding values for previously registered heartbeats and respirations, respectively, stored in memory means not shown.

A corresponding comparison is done in the circuit 11 for the
duration, magnitude and variation of time intervals for true
body movements. Thus, the output signals from the circuits 911 are controlled by said parameters and are supplied to
input terminals of a correlator 12 in which heartbeat-related
changes, respiration-related changes and true body movement
changes are correlated. Since a direct relationship exists
between the parameters and the degree of wakefulness, the
parameter values will change upon e.g. a reduced degree of
wakefulness. By means of a threshold detector circuit 13,
such a threshold for the degree of wakefulness can be preset,
at which an alarm is triggered, which activates an alarm
device 14 in the f rm of e.g. an alarm bell r an alarm lamp
or both, if suitable. 15 designates a visual presentati n
devic , e.g. a screen.

CLAIMS

- 1. A method of monitoring and estimating a person's wakeful-5 ness and, thereby, drowsiness, characterized in - that an electric signal is generated in response to said person's body movements relative to at least one stationary pressure sensitive means which contacts at least a portion of said person's body,
- 10 that signals are separated from said electric signal in correspondence to the duration and magnitude of true body movements, the amplitude of heartbeat-related body movements as a function of rate, and the amplitude of respirationrelated body movements as a function of rate,
- 15 that the duration and magnitude of said true body movements as well as the time-interval between same are measured and compared with previously measured corresponding values to determine possible changes,
- that the amplitude of every heartbeat-related and every 20 respiration-related body movement as well as the time-interval between at least two successive heartbeats and respirations, are measured and compared with previously measured corresponding values to determine possible changes,
- that heartbeat-related and respiration-related changes are 25 correlated with true body movement changes,
 - that the resulting change is compared with a preset wakefulness threshold and
 - that an alarm is triggered when the threshold is reached as an indication of a reduced degree of wakefulness.

30

- 2. An apparatus for monitoring and estimating a person's wakefulness and, thereby, drowsiness, characterized by - at least one stationary pressure sensitive means (2, 3, 4) which is adapted to contact at least a portion of said per-35 son's (1) body, and to generate an electric signal on its
- output terminal in response to said p rs n's body movements relative to same,
 - a detector/filter circuit (5), conn ct d to the output terminal of said at least one stationary pressure sensitive

- means (2, 3, 4), and adapted to separate, from said lectric signal, signals corresp nding to the duration and magnitude of true body movements, to the amplitude of heartbeat-related body movements as a function of rate, and to the amplitude of respiration-related body movements as a function of rate, and output these separated signals on corresponding output terminals,
- a first calculation and comparison circuit (8, 11) which is adapted to receive, on its input terminal, said signal corresponding to true body movements, to calculate the duration and magnitude of the true body movements as well as the time interval between same, and to compare these calculated values with previously calculated corresponding values to determine possible changes,
- 15 a second and a third calculation and comparison circuit (6, 9 and 7, 10, respectively) which are adapted to receive, on their input terminals, said signal corresponding to heartbeat-related and respiration-related body movements, respectively, to calculate the amplitude of every heartbeat-related and every respiration-related body movement, respectively, as well as the time interval between at least two successive heartbeats and respirations, respectively, and to compare these calculated values with previously calculated corresponding values to determine possible changes,
- a correlator (12), connected to the the output terminals of said three calculation and comparison circuits (6, 9; 7, 10; 8, 11), and adapted to correlate heartbeat-related and respiration-related changes with true body movement changes, a threshold detector circuit (13), connected to the output terminal of the correlator (12), and adapted to compare the resulting change with a preset wakefulness threshold, and an alarm device (14), connected to the output terminal of the threshold detector circuit (13), and adapted to trigger alarm when the preset threshold is reached as an indication of a reduced degree of wakefulness.
 - 3. Apparatus according to claim 2, characteris d in that at least one pressur sensitive means (2, 3, 4) comprises at least on pressure sensitive plate f PVDF film.

PCT/SE95/00629

4. The apparatus according to claim 2, characterized in that said at least one pressure sensitive means (2, 3, 4) comprises at least one pressure sensitive plate of PVDF film in combination with at least one electrostatic plate.

5

5. The apparatus according to any of claims 2-4, characterized in that said at least one pressure sensitive means (2, 3, 4) is installed in the seat and/or the back rest and/or the safety belt in a vehicle, in a bed, etc.

10

- 6. The apparatus according to claim 2, characterized in that said alarm device (14) is adapted to generate an audio signal.
- 7. The apparatus according to claim 2, characterized in that said alarm device (14) is adapted to generate a light signal.
- 8. The apparatus according to claim 2, characterized in that said alarm device (14) is adapted to generate an audio signal as well as a light signal.

WO 95/33403 PCT/SE95/00629

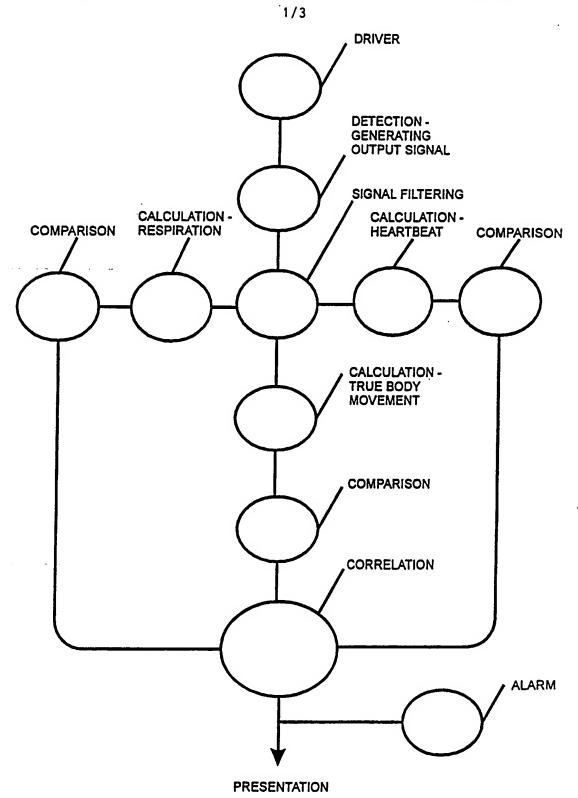
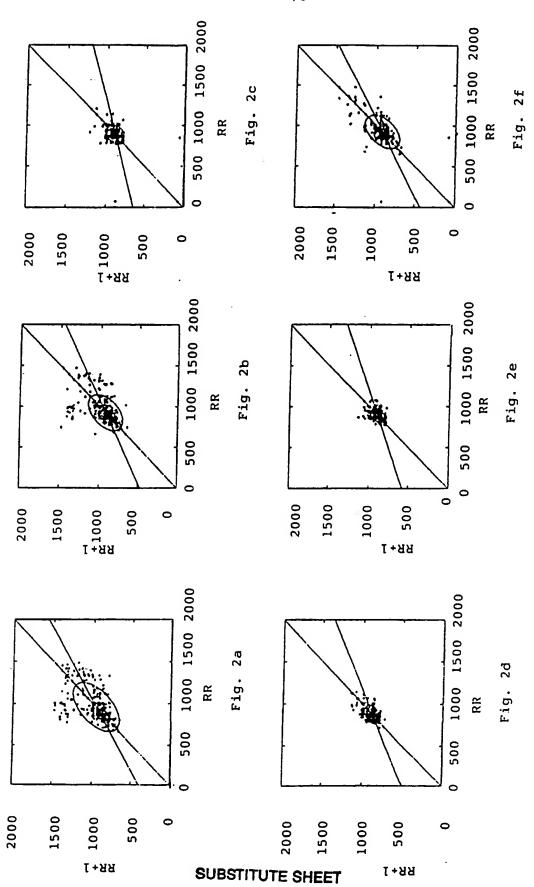


Fig. 1





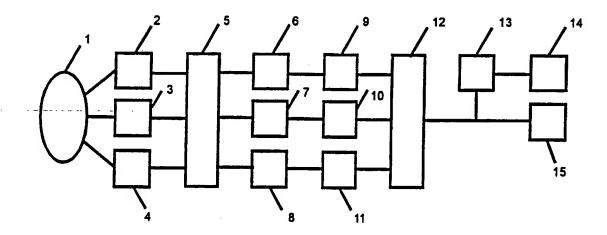


Fig. 3

International application No.

PCT/SE 95/00629 A. CLASSIFICATION OF SUBJECT MATTER IPC6: A61B 5/0205 According to International Patent Classification (IPC) or to both national classification and IPC B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched SE, DK, FI, NO classes as above Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) **EPODOC** C. DOCUMENTS CONSIDERED TO BE RELEVANT Category* Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. A US 5280791 A (LAVIE), 25 January 1994 (25.01.94) 1-8 A DE 4035292 A1 (SCHAUF, GERHARD), 13 June 1991 1-8 (13.06.91), abstract A EP 0267737 A2 (SYRINX INNOVATIONS LIMITED), 3-4 18 May 1988 (18.05.88) A EP 0450341 A2 (HEWLETT-PACKARD COMPANY), 1-8 9 October 1991 (09.10.91), figures 1,2, abstract X Further documents are listed in the continuation of Box C. See patent family annex. Special categories of cited documents: later document published after the international filing date or priority date and not in conflict with the application but cited to understand document defining the general state of the art which is not considered the principle or theory underlying the invention to be of particular relevance "E" erlier document but published on or after the international filing date "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other step when the document is taken alone special reason (as specified) "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is "O" document referring to an oral disclosure, use, exhibition or other combined with one or more other r such documents, such combination document published prior to the international filing date but later than being obvious to a person skilled in the art the priority date claimed "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 22 -09- **1**995 <u> 20 Sept 1995</u> Name and mailing address of the ISA/ Authorized officer Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Tycho Beckman Facsimile No. +46 8 666 02 86 Telephone No.

+46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

International application No.
PCT/SE 95/00629

	PCT/SE 9	95/00629
C (Continu	ation). DOCUMENTS CONSIDERED TO BE RELEVANT	
Category*	Citation of document, with indication, where appropriate, of the relevant passage	Relevant to claim No
A,P	US 5353013 A (ESTRADA), 4 October 1994 (04.10.94), abstract	1-8
A	EP 0371424 A1 (MADAUS MEDIZIN ELEKTRONIK GMBH & CO. KG.), 6 June 1990 (06.06.90), figure 1, abstract	1-8
A	US 4203098 A (MUNCHERYAN), 13 May 1980 (13.05.80), abstract	1-8

INTERNATIONAL SEARCH REPORT

Information on patent family members

28/08/95

International application No.
PCT/SE 95/00629

Patent document cited in search report		Publication date		ent family nember(s)	Publication date	
JS-A-	5280791	25/01/94	IL-A-	100080	29/12/94	
DE-A1-	4035292	13/06/91	NONE		,	
P-A2-	0267737	18/05/88	AU-A- JP-A-	8064887 63167264	12/05/88 11/07/88	
P-A2-	0450341	09/10/91	JP-A- US-A-	4269939 5187657	25/09/92 16/02/93	
JS-A-	5353013	04/10/94	NONE			
EP-A1-	0371424	06/06/90	SE-T3- AT-T- AU-B- AU-A- CA-A- DE-D- ES-T- JP-A- US-A-	0371424 106218 623705 4551989 2004293 58907771 2054992 2305552 4982738	15/06/94 21/05/92 07/06/90 31/05/90 00/00/00 16/08/94 19/12/90 08/01/91	
IS-A-	4203098	13/05/80	NONE			